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GOOD PRACTICE FOR MARKET SURVEILLANCE

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This guidance document - developed by market surveillance experts who are members or Chairpersons of various Administrative Cooperation (AdCo) groups - reflects good practice in the field of market surveillance and aims to contribute to a better understanding and consistent application of EU rules on market surveillance of non-food products across different sectors. The information provided is of a general nature only and doesn't specifically address any particular individual or entity. Only the text of the Union applicable legislation itself has legal force and only the Court of Justice of the EU has the competence of interpreting EU legislation in a binding manner.

This document is intended for market surveillance authorities, in sectors falling under the scope of Regulation (EC) No 765/2008 on Accreditation and Market Surveillance. However, it can be used, for information, by any other interested parties or for any other sector where market surveillance is required.

As the document reflects the state of the art at the moment of its drafting, it may be subject to later modifications.

1. INTRODUCTION

The document was commissioned by the AdCo Chairpersons group in order to develop good practice for market surveillance for products applicable 'horizontally' to different sectors. The document was developed by market surveillance experts from different European countries and sectors of Union harmonised legislation¹.

SCOPE AND TARGET AUDIENCE

The purpose of this document is to provide guidance to Market Surveillance Authorities in the EEA responsible for market surveillance in sectors within the scope of Regulation (EC) No 765/2008². This guidance is also expected to be relevant for Swiss Market Surveillance Authorities competent in sectors within the scope of the EU-Switzerland Mutual Recognition Agreement³. It is intended to be a working tool which will help to facilitate effective cross border market surveillance and provide a common understanding of the procedures laid down in applicable EU legislation ensuring a consistent approach to market surveillance.

The document covers:

- the procedural steps described in Regulation (EC) No 765/2008 on market surveillance for products covered by Union harmonisation legislation. The Regulation directly applies to Member States and national authorities.
- where applicable, the market surveillance provisions described in Decision No 768/2008/EC on a common framework for the marketing of products⁴ and incorporated in sectoral legislation aligned to it.

The relevant market surveillance provisions are described in Chapter 7 of the Blue Guide⁵.

The document primarily addresses market surveillance carried out in relation to Union harmonisation legislation as listed in Annex I. For chemicals in scope of the REACH Regulation, this document needs to be complemented by specific guidance developed by ECHA and the Forum. The document does not attempt to cover the General Product Safety Directive No 2001/95/EC⁶.

DEFINITION OF MARKET SURVEILLANCE

Market surveillance is defined by Regulation (EC) No 765/2008 as the activities carried out and measures taken by public authorities to ensure that products comply with the applicable requirements and do not endanger health, safety or any other aspect of public interest

1 Sectors represented were: Machinery, Personal protective equipment, Construction Products, Toys, Radio Telecommunications Equipment, Low Voltage, Measuring instruments and Non-Automatic Weighing Instruments, Equipment for use in Potentially Explosive Atmospheres, Electro-magnetic Compatibility, Recreational Craft, Pressure Equipment and Simple Pressure Vessel, Energy Labelling, Eco-design.

2 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765>

3 The consolidated version of the agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (OJ L 114, 30.4.2002, p. 369-429). can be found at [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002A0430\(05\)-20150414](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002A0430(05)-20150414)

4 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0768>

5 http://ec.europa.eu/growth/single-market/goods/building-blocks/index_en.htm or

<http://ec.europa.eu/DocsRoom/documents/12661/attachments/1/translations/en/renditions/native>.

6 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4) .

protection. These applicable requirements are contained in Union harmonisation legislation, laying down rules on marketing products.

One of the fundamental freedoms of the European internal market is the free movement of goods. Economic Operators of non-food goods can often bring their products to the internal market without needing prior approval by a Market Surveillance Authority. However, they must ensure that the products meet all legal requirements. Market surveillance verifies this and allows measures restricting the movement of non-compliant products in the EU. By doing so market surveillance guarantees the protection of all aspects of public interests, such as the health and safety of persons or the environment, while also ensuring fair competition.

Market surveillance activities can be carried out proactively, on the Market Surveillance Authority's initiative, or reactively, following accidents, complaints or other intelligence requiring investigation. Formal market surveillance measures can only be addressed once a product has been placed on the market, put into service or presented to customs with a view to be released for free circulation⁷. However a Market Surveillance Authorities may also encourage compliance by providing information on applicable legislation (e.g. via press releases, dedicated websites or information campaigns) at any stage of the design and production process and carry out checks at trade shows fairs and exhibitions⁸.

2. KEY PRINCIPLES

Effective market surveillance is based on several key principles which should be considered whether the activities performed are proactive or active.

STRATEGY FOR MARKET SURVEILLANCE

Market surveillance is not about checking every single product on the market but is about working efficiently and intelligently in order to monitor a wide range of products with the available resources. Intelligent market surveillance considers the appropriate targeting of products, the appropriate actions to perform controls, and the most effective follow-up measures. Furthermore, market surveillance can be carried out both proactively and reactively depending on how to most effectively meet objectives.

PROPORTIONALITY

Article 18(4) of Regulation (EC) 765/2008, requires Member States to ensure that market surveillance activities are exercised with respect to the principle of proportionality. It requires Market Surveillance Authorities not to go beyond what it is necessary for achieving the expected result. In practice, this means that when deciding on corrective actions Market Surveillance Authorities should take into account the level of non-compliance and possible impact e.g. severity of harm and probability of occurrence.

CROSS BORDER COOPERATION

Cooperation between Market Surveillance Authorities from different Member States is

⁷ These concepts are defined in the Glossary. See Chapter 2 of the Blue Guide for further clarifications of these concepts.

⁸ See Chapter 7.2 of the Blue Guide .

essential to effective market surveillance. Cooperation starts with timely exchange of information on draft inspection plans required under Article 18(5) of Regulation (EC) No 765/2008, which should result in efficient coordination of complementary efforts (see section 3.1.3 below). Article 24 of the Regulation compels Market Surveillance Authorities to provide assistance upon request and exchange information and documentation, while Article 23 establishes a common database to share market surveillance information⁹. Market Surveillance Authorities should also follow up on restrictive measures adopted by other Market Surveillance Authorities to ensure effective enforcement across the single market¹⁰. Furthermore, they should attend and actively participate in Administrative Cooperation groups (AdCos¹¹) meetings and as far as possible participate in common projects and joint market surveillance actions.

TARGETING THE RELEVANT ECONOMIC OPERATOR

Most of the legislation listed in Annex 1 contains clear obligations for Economic Operators, proportional to the role they are playing in the supply chain. These obligations are described in detail in Chapter 3 of the Blue Guide.

In order to maximise the effectiveness of market surveillance in the EU Market Surveillance Authorities should always request corrective actions from the Economic Operator (either the manufacturer or the importer) responsible for placing the non-compliant product on the EU/EEA market. This request should be made before or in parallel to addressing the national distributor (i.e. any person in the supply chain, of the product other than the manufacturer or importer, who makes the product available on the market)¹². Addressing the manufacturer or the importer should ensure that corrective actions are taken at EU/EEA level¹³. For sectors falling under the Mutual Recognition Agreement on Conformity Assessment between the EU and Switzerland, Market Surveillance Authorities should address non-compliance within the EEA as well as Switzerland. Against this background, references to the EU in the rest of this document will need to be interpreted as broader references to the EEA and, if appropriate, to Switzerland.

3. MARKET SURVEILLANCE PROCESS / DESCRIPTION

The following flow chart summarises market surveillance activities, detailed descriptions of which can be found in the following sections.

For all sectors, the process of market surveillance can be described in several horizontal steps. Firstly, the Market Surveillance Authority has to determine which products and/or Economic Operator will be targeted to achieve the greatest impact on the market (see “Targeting – 3.1”). The Market Surveillance Authority must then apply this strategy in the

⁹ Further information on the ICSMS database can be found in section 2.2 of the Toolbox.

¹⁰ Further details on the procedure for cross-border cooperation can be found in Annex 2.

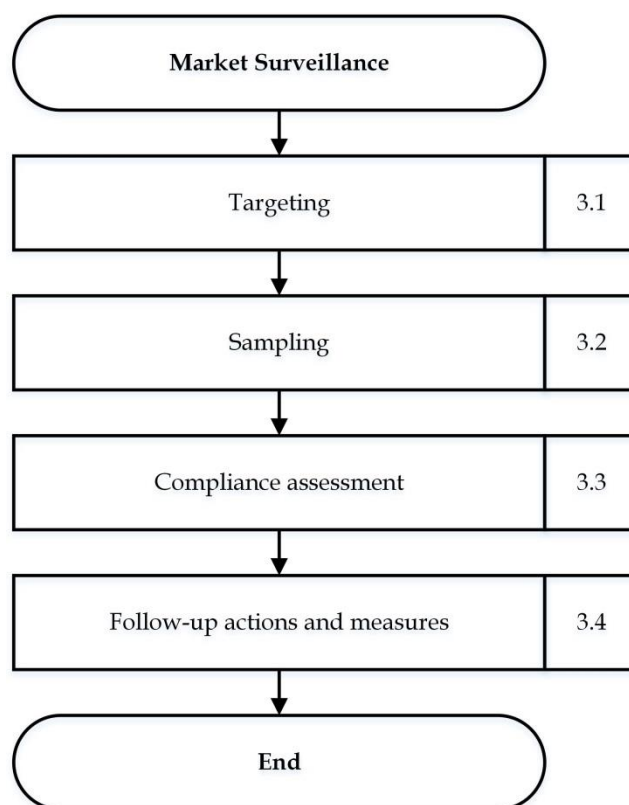
¹¹ Further information on AdCos can be found in section 2.1 of the Toolbox and also via http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/index_en.htm

¹² Further details on the importance of requesting cooperative corrective action at the highest possible level of the supply chain and relevant legal basis can be found in Annex 2.

¹³ The manufacturer or the importer is responsible for taking necessary corrective measures when informed that a product is non-compliant.

field and take samples when relevant (see “Sampling – 3.2”). The Market Surveillance Authority then has to assess compliance which may require requesting more information from the Economic Operator e.g. access to technical documentation (see “Compliance assessment – 3.3”). At the end of the assessment the Market Surveillance Authority is able to draw informed conclusions on the compliance of the type of product. For this stage, and before making a definitive decision, discussion with the relevant Economic Operators needed (see “Follow-up actions and measures – 3.4”). All information gathered throughout the process is valuable and should inform future market surveillance activities.

For each stage of market surveillance, the toolbox found in Annex 5 contains useful guidance, documents and templates to support market surveillance officials.



3.1. TARGETING STAGE

Intelligent and resource efficient market surveillance enhances assessing the compliance of products on or entering the market. Market Surveillance Authorities should prioritise resources to ensure that the actions they take contribute effectively to the protection of public interests and fair markets. When planning market surveillance activities it is important to decide where to sample products from or which Economic Operator to focus on.

There are two distinct types of market surveillance:

- Proactive market surveillance - planned market surveillance activity
- Reactive market surveillance - in response to an outside event

3.1.1. Proactive market surveillance

a) Knowledge of the market

It is recommended that Market Surveillance Authorities perform a market screening exercise to identify which Economic Operators are active in a particular sector; what products are available and where e.g. in store or online. Market Surveillance Authorities are advised to cooperate with industry to identify supply chains and market share and conduct market research among end users. Third party services may also be used to provide information if it can be established as being reliable. At the end of the market screening exercise the Market Surveillance Authority should have an intelligence led overview of:

- the overall size of the national market, i.e. the amount and type of products supplied on the market
- the names and market share of the Economic Operators supplying given products
- the type of Economic Operator (e.g. manufacturers, importers, distributors) and main channels of sales (e.g. online or retail premises).

The Market Surveillance Authority must decide which Economic Operators and products should be targeted to achieve the most effective outcome.

When targeting Economic Operators in a given sector, priority should be given to those that are most likely to break the rules, that do not follow the rules, or that have a history of non-compliance rather than targeting Economic Operators based on random selection¹⁴. Feedback from industry, consumer organisations, trade unions, labour inspectorates, media, consumer complaints and statistical data can provide a useful source of information when making these decisions.

Market Surveillance Authorities should also consider specific tools that can be used to assess an Economic Operator's expected level of compliance or their willingness to comply. An example of this is the 'Table of Eleven' which has been developed for a national authority in the field of criminal law¹⁵.

When targeting products in a given sector, priority should be based on the number and severity of non-compliant products found on the market. To maximise effectiveness and efficiency of market interventions whenever possible the Market Surveillance Authority should focus on targeting products produced in large quantities instead of a single product or targeting products that have the potential to have high impacts on health and safety of consumers, users or the environment. Targeting shipments at ports of entry can also be an efficient use of resources as it can prevent non-compliant products from entering the EU market and avoid more costly actions once the product is in the distribution chain. If products are manufactured in and have been placed on the EU market, targeting products at distributor's sites (in particular wholesalers) is also an efficient and effective way of sampling. Inspecting large or industrial products (which are often supplied individually and may not be assembled until they reach the end user e.g. a factory) may not be fully possible

¹⁴ Random selection may be beneficial where little information is available on a sector e.g. emerging technologies.

¹⁵ See section 3.1.1 of the Toolbox.

prior to assembly or installation.

Cooperation at an early stage with custom authorities should also be systematic when specific Economic Operators who import the targeted products are identified.

Some Economic Operators might only offer products online, without having them in stock. The European Commission is developing guidance relating to how to perform e-commerce investigations.

b) Planning activities

Proactive market surveillance refers to activities which are specifically planned, organised and implemented by the Market Surveillance Authority.

Proactive market surveillance activities are important because they have the potential to prevent non-compliance from taking place. It is more cost-efficient than reactive market surveillance because the resources and the parameters needed to carry out these activities can be defined in advance. These activities can also include long-term planned actions for specific products, product groups or sectors such as raising awareness through communication activities or with Economic Operators involved in compliance schemes when they exist.

Article 18(5) of Regulation (EC) 765/2008 states that “Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the European Commission and make them available to the public, by way of electronic communication and, where appropriate other means.” This exchange of information can facilitate cooperation and sharing of resources between Market Surveillance Authorities in different Member States and avoid duplicating activities. It is therefore important that information on planned market surveillance activities is exchanged as early as possible¹⁶. Non confidential information about market surveillance activities and programs is also made publicly available via the European Commission’s website¹⁷.

Proactive market surveillance can relate to either the targeting of Economic Operators (based on criteria such as history of non-compliance, results of audits, market share, distribution of products and / or users, etc.) or the targeting of products, both of which can be conducted as part of a focussed market surveillance campaign. Once an Economic Operator or a product has been selected the process of inspection in line with national legislation to ensure legal requirements are met can begin.

Where the effects of non-compliance are not immediately identifiable (e.g. toxicological or ergonomic hazards such as chronic health issues) proactive market surveillance is preferable.

¹⁶ In practice two complementary tools are available to exchange information on planned activities. Market Surveillance Authorities can informally share ideas about future initiatives in a given sector as well as communicating preliminary sectoral plans to the European Commission via their national coordinator. These plans are then uploaded to CIRCABC under the Internal Market for Products - Market Surveillance Group (IMP-MSG) section. This is available to all EU Market Surveillance Authorities and requests for access can be sent to grow-b1@ec.europa.eu.

¹⁷ http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

c) Implementation of market surveillance campaigns

After having defined scope (e.g. which and how many products or Economic Operators to target) of a specific market surveillance campaign, the Market Surveillance Authority will still need to:

- Define objectives to verify that products are compliant with the applicable legislation in order to guarantee consumer protection and to stop unfair competition
- Define the depth of the compliance evaluation to be carried out¹⁸
- Determine the period during which the campaign will be performed
- Conduct a feasibility study to evaluate if there is sufficient resource to meet the defined scope and objectives of the campaign
- Determine which procedures to follow e.g. by developing a code of practice¹⁹ which will enable the effectiveness of a campaign and facilitate the preparation of a standardised report.

In the course of the campaign the Market Surveillance Authority will evaluate the non-compliance and risk and take the necessary measures against the Economic Operator.

At the end of the campaign the Market Surveillance Authority will produce a report and disseminate the findings of the campaign to stakeholders (e.g. business, industry, Economic Operators consumers, other Market Surveillance Authorities etc.) via appropriate and accessible media channels. It will also perform appropriate follow up measures.

Market surveillance campaigns can be conducted at a national level or jointly with other Member States. Joint market surveillance campaigns are strongly recommended as they improve the effectiveness of national efforts on the Single Market and can reduce costs. Administrative Co-operation Groups (AdCos) can play a key role in the organisation of these campaigns. To encourage joint market surveillance campaigns the European Commission offers financial support for actions that fulfil certain requirements and which are selected under the relevant grant procedures.²⁰

3.1.2. Reactive market surveillance

Not all market surveillance activities can be planned in advance. Reactive market surveillance is normally triggered by an outside event and in relation to a specific suspected offence. This could include incidents and accidents²¹, notifications from other Market Surveillance Authorities through Rapex and ICSMS, notifications from other authorities (e.g.

18 Market Surveillance Authorities for instance can choose to carry out an *extensive* compliance evaluation involving administrative verification and sampling, technical verification including testing/inspection by (internal or external) laboratory/inspection bodies (where no conflicts of interest exist). Alternatively they can conduct a *limited* compliance evaluation involving administrative verification and/or sampling and internal testing (visual) of easily feasible requirements for which no or simple equipment is needed (e.g. measuring the reflective surface of visibility clothing or measuring the length of a cord in a toy).

19 Example of Codes of Practice can be found in the toolbox.

20 Calls for proposals can be found via http://ec.europa.eu/growth/contracts-grants/calls-for-proposals/index_en.htm and http://ec.europa.eu/chafea/consumers/consumers_calls.html.

21 Article 18(2b) of Regulation (EC) No 765/2008.

customs²², labour inspectorate, police, social inspector, transport authority) or notifications from external sources (e.g. consumer complaints, Economic Operators, Notified Bodies, press releases, consumer reports)²³. Information received by a Market Surveillance Authority relating to a product suspected to be non-compliant or to present a risk must be followed up in accordance with the principle of proportionality. In order to avoid duplication, a Market Surveillance Authority should check ICSMS and any other appropriate platforms (e.g. national databases) to see if the same product has already been assessed.

Although reactive market surveillance can create a sense of urgency (as the product might be suspected of having caused an accident) and may attract media interest, Market Surveillance Authorities should act proportionately and reach a considered and justifiable decision.

3.2. SAMPLING STAGE

To assess compliance Market Surveillance Authorities often need to take samples of products. Article 19(1) of Regulation (EC) No 765/2008 provides the legal basis to ensure that Market Surveillance Authorities may take samples and request the documentation and information necessary for carrying out their activities.

During the sampling stage Market Surveillance Authorities need to define the appropriate number of samples and where they should be taken. The Market Surveillance Authority's approach to sampling will be made on a case by case basis depending on the legislation, the type of product, the type of non-compliance being considered, and the number of products on the market.

A primary factor in deciding the sampling strategy is the type of non-compliance being considered. If it is a design or production issue e.g. the lack or wrong type of safety device being fitted, then one model is sufficient. If the Market Surveillance Authority wishes to assess the compliance of a product category that is statistically representative setting the sampling strategy will require knowledge of the size of the product population, which may range from one item (e.g. a large industrial machine) to thousands being available.

a) When and where to take samples

Samples are usually taken from the Economic Operator if a Market Surveillance Authority has doubts on the compliance of a product, during a market surveillance campaign or as part of reactive market surveillance.

Samples may be obtained from various locations, either online or directly from the manufacturer, importer or distributor. Depending on the product the Market Surveillance Authority may consider it appropriate to inspect specific samples at the end-users premises. This will normally be the case for large industrial products.

It might be efficient to take samples and all related necessary documents (e.g. the EU Declaration of Conformity, Instructions for use etc.) from the Economic Operator responsible

²² Regulation (EC) No 765/2008 (Chapter III, Section 3 provides the legal basis to act on notifications from customs.

²³ Article 18(2a) of Regulation (EC) No 765/2008.

for placing the product on the market. This should allow faster and more comprehensive measures to be taken to address cases of non-compliance.

The Market Surveillance Authority will decide which samples to obtain from those available. Samples are usually taken without prior announcement to the Economic Operator concerned. Mitigating the risk of non-representative samples being supplied and ensuring that the samples correspond with those freely available on the market.

National legislation dictates whether or not the Market Surveillance Authority has to pay for the samples taken. If national legislation requires the Market Surveillance Authority to pay, the Economic Operator must issue a receipt for the products purchased. If national legislation does not require the Market Surveillance Authority to pay, the samples remain the property of the Economic Operator and the Market Surveillance Authority will issue a sampling form.

b) Number of samples

The number of samples defined in the scope of the campaign must be sufficient for the planned assessment and testing. It is important to note that the aim of inspection and testing by the Market Surveillance Authority is to check whether a product is compliant or not.

Where a Market Surveillance Authority inspects the product according to the 'Essential Requirements' in the relevant Directive or Regulation the number of samples requested by the Market Surveillance Authority depends upon the complexity of the product and required steps for the testing of the product. This is because some tests may destroy the product and if further tests are necessary more samples of the product will be needed. Also for legal reasons (depending on national legislation) it may be necessary to have a further sample that is "sealed" and available for independent additional testing if required. Prior exchange of information with the laboratory technicians who will be in charge of the testing is recommended to clarify these aspects.

It is the Market Surveillance Authority's responsibility to demonstrate the non-compliance of the samples taken. It is the responsibility of the Economic Operator to demonstrate to the Market Surveillance Authority whether or not only the specific samples and not the entire production series are non-compliant.

For market surveillance it is only necessary to use a statistical approach to sampling if a campaign aims to find a result representative for a certain product group. In this case sampling includes defining the "batch of products" from which the sample is drawn.

c) Handling of the samples

When handling samples, consideration to continuity of evidence is critical and the Market Surveillance Authority must ensure that:

- the samples taken are packaged and stored in a way that precludes tampering and damage
- the samples are unequivocally identifiable and auditable e.g. through clear labelling and recording system.

- all required information about the samples is collected and recorded properly. A sampling form²⁴ should contain detailed identification of the samples, such as data on the label, the number of samples taken (based on technical specifications, standards), photographs of the samples, location of examination, date the samples were taken, name and signature of the inspector, name and signature of the Economic Operator's representative and any other necessary comments. Relevant information should then be uploaded to a national database such as ICSMS or international equivalent.

It is critical that the samples are correctly handled, appropriately sealed, secured, and are fully traceable at each stage, from taking the sample to testing the sample. Any secure seals applied to the samples should only be removed and subsequently recorded, when testing commences.

Consideration should be given to samples of products (e.g. dangerous chemicals, fireworks) the transport and storage of which are regulated. The necessary authorisations or the use of specially habilitated transport / storage service may be needed and should be planned ahead.

d) Sampling of large products

A Market Surveillance Authority might not consider it to be appropriate or cost effective to sample large products or those supplied in low numbers and instead must identify which elements of the product are representative for the products compliance. The Market Surveillance Authority might consider it sufficient to carry out a detailed examination of a specific part of a large product.

In the case of large products it may be appropriate to keep and inspect the product at either the Economic Operator's or the end-users site. This will necessitate the Market Surveillance Authority to use appropriate powers provided under national legislation to obtain access to and seal the product ensuring that the product remains unchanged during the investigation, inspection and testing process.

3.3. COMPLIANCE ASSESSMENT

It is the Economic Operators responsibility, according to their respective role in the supply chain, to ensure compliance with all relevant legislation and to fulfil all appropriate conformity assessment obligations.

The task of the Market Surveillance Authority is to verify whether a product complies with the requirements of the applicable legislation. However the Market Surveillance Authority should not issue a compliance statement which could be seen as endorsing a product.

When assessing the compliance of a product, the Market Surveillance Authority may choose to consider all relevant legislative requirements (a *full compliance assessment*) or parts of them (a *partial compliance assessment*). The compliance assessment may be divided between 'Formal' compliance (administrative requirements e.g. documentation, markings, etc.) and

²⁴ An example can be found in section 3.2 of the Toolbox.

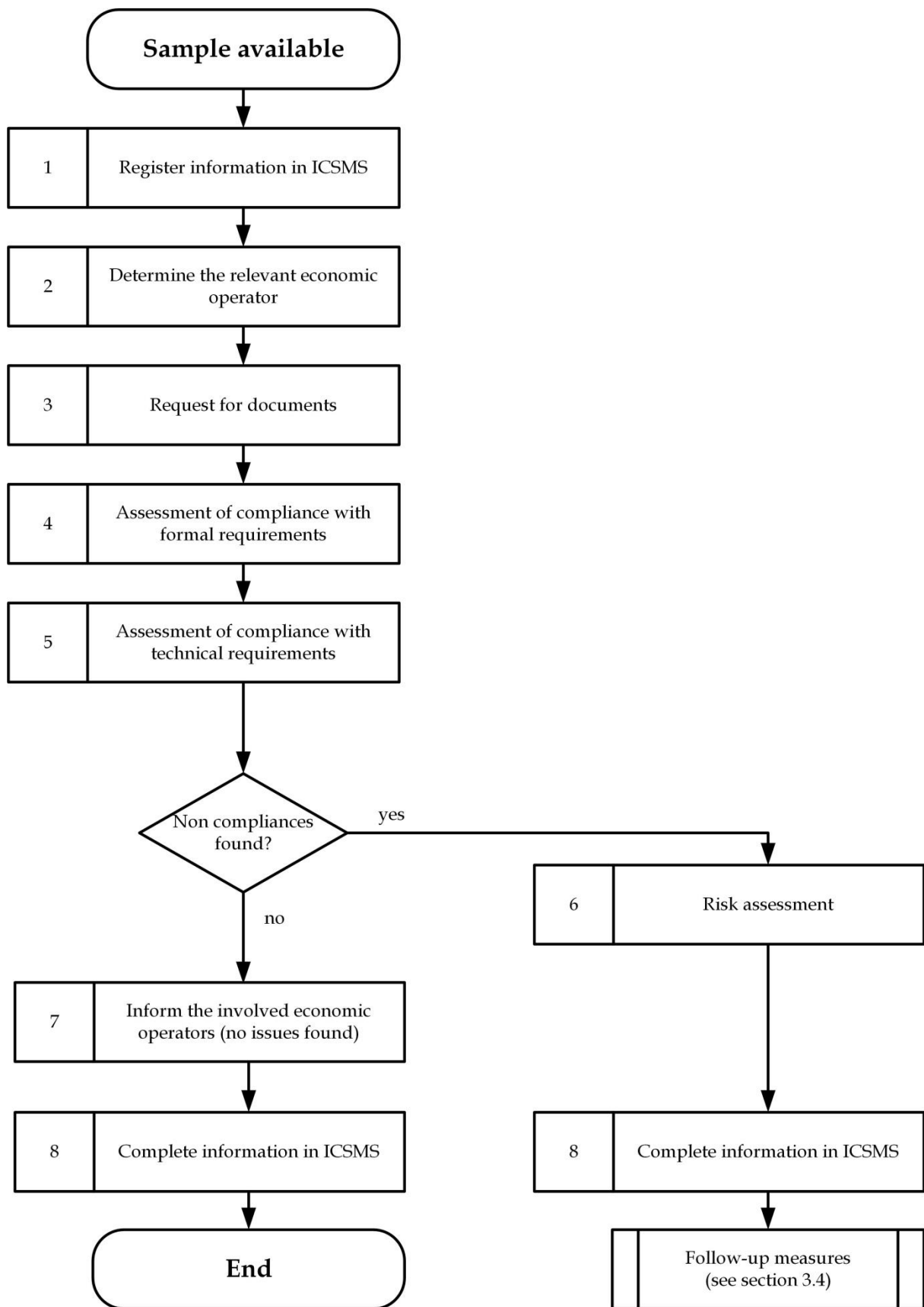
‘Technical’ compliance (essential requirements)²⁵.

Market Surveillance Authorities should exchange views on how the various requirements are to be assessed to ensure consistency regardless of which Market Surveillance Authority has assessed the product. Therefore, benchmarking exercises could be organised via AdCos whereby members assess the same product to provide comparable outcomes. Common checklists developed by AdCos may be used to facilitate the compliance assessment for specific product groups²⁶. For a compliance assessment and risk management to be effective the Market Surveillance Authority must have access to complementary information such as the date the sample was placed on the market (to determine the accuracy of the Economic Operator’s conformity assessment) and information on the quantity of products sold and in the distribution chain.

The compliance assessment will begin once an inspection has been carried out or a sample or document has been made available. The following flowchart outlines the process between the collection of a sample and the determination of any subsequent follow-up measures. The steps identified in the flowchart presume that the Market Surveillance Authority will carry out a full compliance assessment according to the relevant legislation. It is important to remember that the steps described in the flowchart may vary depending on the product being assessed and the campaign itself.

²⁵ These terms refer to the requirements assessed by the Market Surveillance Authority, not the risk of the product as a consequence of non-compliance.

²⁶ See document 3.1.2b in section 3.1.2 of the Toolbox and documents in section 3.3.1 of the Toolbox.



3.3.1. Step 1: Register information in ICSMS

The Market Surveillance Authority should check whether the product to be assessed is already registered on ICSMS. If so it might be useful to verify the Product Information (PI) details and to contact the processing Market Surveillance Authority.

If a PI does not already exist, the relevant information about the product should be recorded in ICSMS promptly. This is necessary as other Market Surveillance Authorities should be informed in a timely fashion that the product, which may be available in other Member States, is being assessed to avoid unnecessary duplication.

In the case of mass products, where a high number of initial checks take place, it may not be feasible to encode in ICSMS information on all investigations carried out. However encoding should take place at very least when the authority has reason to believe that the same product has also been made available in other Member States or a sample has been taken for examination.

3.3.2. Step 2: Determine the relevant Economic Operator

It is important to quickly determine the manufacturer or importer responsible for placing the product on the market. This enables the Market Surveillance Authority to request information and resolve non-compliance efficiently and in good time.

If there is a manufacturer or importer in the EU, the Market Surveillance Authority should address them directly. If the manufacturer is based outside of the EU, the Market Surveillance Authority should contact its authorised representative if such exists or attempt to contact the manufacturer in the third country.

If the manufacturer or importer is not available or cooperative the Market Surveillance Authority should address the Economic Operators high up in the distribution chain as possible (e.g. the wholesaler or retailer)²⁷.

It should be noted that a product is non-compliant if the name and address of the manufacturer or importer is not present. In such cases, the Market Surveillance Authority should request that the Economic Operator from whom the product was sampled to provide information (such as lists of deliveries, invoices or orders) regarding where the product was purchased in order to identify the highest Economic Operator in the distribution chain.

3.3.3. Step 3: Request for documents

In order to carry out a comprehensive compliance assessment, the Market Surveillance Authority should have detailed information on the product, which is available in the EU

²⁷ Some legislation may foresee additional entities that have obligations to fulfill, as private importer. [Directive 2013/53/EU](#) on recreational craft and personal watercraft foresees that a private importer, before putting the product into service, shall ensure that it has been designed and manufactured in accordance with the requirements set out in the relevant legislation. This means that in general, all the requirements for the Economic Operators apply also to the private importer

declaration of conformity / declaration of performance²⁸ and, if necessary, in the technical documentation²⁹. Requesting the declaration of conformity and technical documentation will usually be done via the relevant Economic Operator or via the highest Economic Operator in the supply chain (see section 3.3.2)³⁰.

In the case of complex industrial products it may not be cost effective or necessary to request technical documentation in full. In such instances the principle of proportionality would imply that the Market Surveillance Authority would not require the complete technical file but only the technical documentation sufficient to support a compliance assessment.³¹

When the Market Surveillance Authority requests technical documentation from an Economic Operator in a different Member State it is recommended to inform the Market Surveillance Authority of the Member State where the Economic Operator is based. If the Market Surveillance Authority is unsuccessful in requesting technical documentation from that Economic Operator, it should then seek the assistance of the Market Surveillance Authority where the Economic Operator is based. This Market Surveillance Authority should provide adequate assistance e.g. by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measures³². Further details on the mutual assistance procedure can be found in Annex 2 (see in particular the proposed general principles and procedure for case 1)³³.

If there is evidence (e.g. identification number on the product and/or the packaging) that a notified body has been involved in the conformity assessment procedure, the Market Surveillance Authority may contact this notified body to ask for more information on its involvement and to obtain information on the conformity assessment procedure.³⁴

Another important source of information is the instructions for use and for some products (e.g. construction products) information on dangerous substances. These usually have to accompany the product and should be available to users. When a compliance assessment is carried out without a sample, instructions for use may be available online. If necessary, they can be requested from the Economic Operator and must be made available to the Market Surveillance Authority.

3.3.4. Step 4: Assessment of compliance with formal requirements

Assessing compliance with formal requirements normally consists of assessing whether:

- the conformity marking has been affixed on the product and/or on its packaging and is in line with legal requirements

28 Most EU legislation requires a Declaration of Conformity; the Construction Products Regulation requires a declaration of performance.

29 An example of letter requesting for documents can be found in section 3.3.3.1 of the Toolbox.

30 The supply chain may not have access to the technical documentation but must assist the Market Surveillance Authority obtain the relevant information from the manufacturer. An example can be found in the toolbox.

31 See section 7.2 of the Blue Guide for further details.

32 The legal basis for this type of mutual assistance is set out in Article 24(2) of Regulation (EC) 765/2008.

33 Templates for informing the Market Surveillance Authority of the Member State where the Economic Operator is based and to request its assistance are provided in section 2.3 of the Toolbox.

34 An example of letter requesting for documents to the Notified Body can be found in section 3.3.3.2 of the Toolbox

- the EU declaration of conformity or performance is available and drawn up correctly
- the technical documentation is available and complete
- the instructions for use and/or installation are available and comprehensible in the language of the user
- other specific elements required by the relevant EU legislation should be considered

Situations where missing or incomplete information (e.g. safety information for the end-user) might lead to a risk should not be considered as formal non-compliance when deciding on the appropriate follow up action (see also step 11 in section 3.4).

The Market Surveillance Authority should consider whether some of the information required to carry out a formal compliance assessment is available online.

When assessing technical documentation, the Market Surveillance Authority should check:³⁵

- that the EU declaration of conformity or performance is available and complete³⁶
- the correctness of the conformity assessment procedure carried out by the manufacturer;
- the validity of the conformity assessment procedure carried out by the manufacturer at the time of placing the product on the market (e.g. a conformity assessment carried out ten years ago may no longer be valid for products sampled by the Market Surveillance Authority);
- whether all documents necessary to support compliance have been made available.

3.3.5. Step 5: Assessment of compliance with technical requirements

Assessing the compliance with technical requirements will establish whether the product is fulfilling the essential requirements or the technical specifications set out in the relevant EU legislation. This is achieved by testing the product either by the Market Surveillance Authority or by an independent third party (e.g. test laboratory). Accreditation of the third party is not mandatory in all sectors but does provide a further guarantee as to the competence of the body. For some products (e.g. large or industrial products) the Market Surveillance Authority may identify non-compliance through a simple visual check. Such items are rarely sent to a third party for assessment but if an independent view is needed an external engineer competent in the aspects being examined could be appointed to give expert evidence on factual aspects of the compliance.

To define which tests to be carry out requires appropriate analysis and depends on numerous variables e.g. the availability of relevant harmonised standards and their application by the manufacturer. Therefore access to the declaration of conformity and/or the technical documentation, which provides information on the manufacturer's conformity

³⁵ See examples of checklist for both formal and technical compliance assessment provided in section 3.3.1 of the Toolbox.

³⁶ Assessing the accuracy of the Declaration of Conformity may only be possible in conjunction with other technical documentation

assessment is essential. It may be necessary to request more information from the manufacturer regarding how to test the product (e.g. to set the product in a test mode).

The results of any test are to be recorded in test reports and the Market Surveillance Authority should also consider the technical documentation when evaluating the results.

Carrying out the compliance assessment will depend on whether a harmonised standard exists and has been used by the manufacturer, if it is by direct reference to the essential requirements, or if the involvement of a notified body is legally required. The following scenarios are therefore possible:

- An EN standard exists but it has not been (fully) applied and some other standards have been used;
- An EN standard has been applied but it does not cover all essential requirements and/or hazards.

It may therefore be possible for a product to comply with a harmonised standard but not the legislation. An effective way of assessing technical compliance is to test the product against a relevant harmonised standard and to evaluate whether compliance with the legislation has been compromised.

The Market Surveillance Authority should also be aware that other standards may be used (e.g. ISO, IEC, national) where EN standards do not exist. It might also be the case that no standard exists. In such cases it might be advisable to agree on an appropriate procedure, either within the AdCos or together with stakeholders.

The Market Surveillance Authority should be aware that the manufacturer is free to choose his own way of demonstrating compliance to the essential requirements. The Market Surveillance Authority should check against the essential requirements as the use of harmonised standards represents the agreed state of the art testing method.

When a notified body has been involved in the conformity assessment it may be appropriate to ask the notified body the extent of that involvement and the documents on which the assessment was based.³⁵

3.3.6. Step 6: Risk assessment

According to the provisions of the EU legislation, the Market Surveillance Authority has to carry out a risk assessment³⁷ (as part of the compliance assessment) as soon as a non-compliant product representing a risk to the health or safety of persons or to other aspects of public interest protection is identified. The Market Surveillance Authority must evaluate the nature and level of that risk and document the result. This is needed to determine the level of risk when notifications are made in both ICSMS and RAPEX where a category for risk must be reported.

³⁷ A Market Surveillance Authority's risk assessment is focussed on the non-compliance found whereas a manufacturer's risk assessment takes into account all relevant hazards and informs the actions needed to reduce risk when a product is designed or produced.

The outcome of the risk assessment should determine the level of the risk and provide the relevant information for the Market Surveillance Authority to issue a proportionate measure when the Economic Operator fails to take appropriate action and decide whether a RAPEX procedure is needed.

A common methodology for the risk assessment of non-compliant products (the EU general risk assessment methodology) has been developed by the Expert Group on the Internal Market for Products – market surveillance group and AdCos.³⁸ The methodology builds on the RAPEX Guidelines³⁹, developed within the framework of the Directive on General Product Safety (GPSD) and extends them in two respects:

- to make sure that the broader categories of public risk protected under EU harmonization legislation can be taken into account;
- to reflect the specific legal requirements on harmonised products. Risk assessment methods could and are being developed for specific sectors or aspects within the common methodology.

3.3.7. Step 7: Inform the involved Economic Operators (no issues found)

If the Economic Operators are aware that their product is being assessed, it is good practice to inform them in writing, of the result, even if no issues have been found. However care must be taken to ensure that the Economic Operator does not misuse this communication as an endorsement or compliance certificate. The communication should never indicate that the product is compliant because the Market Surveillance Authority has not fully assessed the product and the manufacturing process.

3.3.8. Step 8: Complete information in ICSMS

To avoid duplicating investigations it is necessary to provide other Market Surveillance Authorities with relevant information and results of the assessment carried out, the documents received from the Economic Operator and other relevant information via ICSMS as soon as possible.

3.4. FOLLOW UP ACTION AND MEASURES

Following non-compliance the Market Surveillance Authority should request the manufacturer⁴⁰ or the importer responsible for first placing the product on the market, to take corrective actions within a reasonable time limit (unless immediate action is required to

³⁸ This can be found at:

<http://ec.europa.eu/DocsRoom/documents/15261/attachments/1/translations/en/renditions/native> or via http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm under the section "Studies, reports and conclusions of expert groups".

³⁹ Guidelines for the management of RAPEX and the notification procedure established by the General Product Safety Directive provided in Commission Decision 2010/15/EU.

⁴⁰ The manufacturer can be located in the EU or in a third country. If the manufacturer is located in a third country they may be addressed via its authorised representative.

address a serious safety or environmental risk) in accordance with their obligations (i.e. bringing the product into compliance or other corrective action). This should take place before or in parallel to addressing the distributor⁴¹ allowing for corrective actions to be taken at the highest possible level in the single market.

In the first instance the Market Surveillance Authority should request the Economic Operator to undertake corrective actions voluntarily in order to resolve the problem⁴². Corrective actions should be proportional to the risks involved and should aim to resolve the non-compliance for products supplied into all Member States, not only in the Member State where the non-compliance was first discovered⁴³.

This section explains the relevant steps for a Market Surveillance Authority in line with the model provisions (notably model Articles 31 to 34) of Decision No 768/2008/EC on a Common Framework for the Marketing of Products that have been incorporated in all new European harmonisation directives and regulations.

3.4.1. Dealing with non-compliant products

The role of the Market Surveillance Authority is to communicate the nature of the non-compliance to the Economic Operator and ensure that the actions taken are appropriate and carried out in full. Depending on the nature of the non-compliance, the risk involved and the actions of the Economic Operator, it may be necessary to take formal proportionate enforcement action.

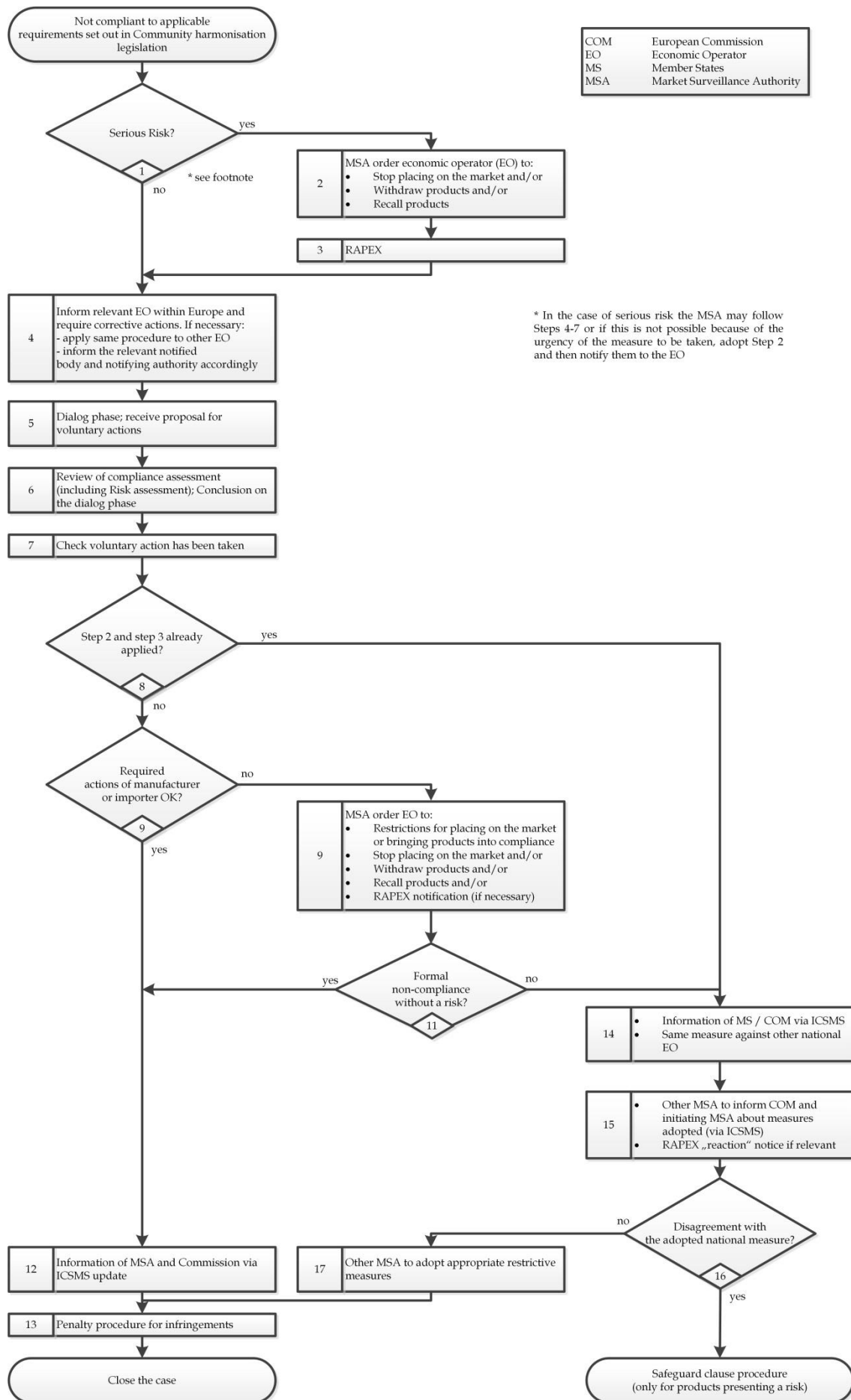
Where an Economic Operator does not take voluntary action, or if voluntary action is considered not suitable to solve the problem or a serious risk is identified, the Market Surveillance Authority shall take all appropriate provisional measures and notify them to the European Commission and other Market Surveillance Authorities unless the non-compliance is restricted only to their own territory. The purpose of the notification is to inform all national Market Surveillance Authorities about non-compliant products presenting a risk, and to have the necessary restrictions extended to all Member States in order to ensure an equivalent level of protection throughout the EU.

The following flowchart explains this process and the necessary steps to be taken when dealing with non-compliant products:

41 Any person in the supply chain other than the manufacturer or importer, who makes the product available on the market.

42 A voluntary action is that undertaken by the Economic Operator before the Market Surveillance Authority requires specific corrective measures. Model Articles R2(8), R4(7) and R5(4) of Decision No 768/2008 (obliges manufacturers, importers and distributors to take corrective measures if aware that products they made available are non-compliant).

43 Article R31(3) of Decision No 768/2008 and corresponding provisions in EU harmonisation legislation obliges the Economic Operator to ensure that appropriate corrective action is taken in respect of all the products concerned that it has made available on the EU market.



Step 1: After the compliance and risk assessment has been carried out the Market Surveillance Authority must decide upon the appropriate follow up measure which will be determined by the seriousness of the risk⁴⁴.

Step 2: Where the product presents a serious risk requiring rapid intervention, including where the effects of the risk are not immediate, the Market Surveillance Authority shall ensure that such products are recalled, withdrawn, their availability on the market prohibited or restricted or that the Economic Operator takes other appropriate corrective action.

If immediate voluntary measures cannot be agreed and undertaken in a timely manner by the Economic Operator then formal mandatory action will be required. In case of urgency it may also be appropriate to take action prior to giving the Economic Operator the opportunity to make their views known. In this situation the Economic Operator shall be given the opportunity to make their case as soon as possible and the action taken shall be subsequently reviewed.

Step 3: Measures taken against products presenting a serious risk require a notification via the EU Rapid Alert System (RAPEX) which was established under Article 12 of Directive 2001/95/EC (the General Product Safety Directive) and extended to all harmonised products by Regulation (EC) 765/2008⁴⁵.

Step 4: Where the product does not present a serious risk (or where rapid corrective actions have been taken nationally to resolve a non-compliant product presenting a serious risk) the Market Surveillance Authority shall immediately inform the Economic Operator about the non-compliance of the product. The Market Surveillance Authority will seek to understand the reasons for non-compliance and commit the Economic Operator to take all appropriate corrective actions to either bring the product into compliance, to withdraw the product from the market, or to recall it within a reasonable period. It is essential that the Economic Operator is requested to reply in a specified reasonable time. The Market Surveillance Authority must consider whether it is also necessary to inform relevant notified body(s) and notifying authorities (if necessary).⁴⁶

The Market Surveillance Authority should contact the relevant Economic Operator in the Union even if they are not located in their own jurisdiction, requesting that necessary voluntary corrective actions are taken.⁴⁷

If the Economic Operator does not cooperate then the Market Surveillance Authority will adopt restrictive measures within its national territory and invoke the Safeguard Clause Procedure. Cross-border cooperation (see Annex 2) becomes essential in this case.

Step 5: The Economic Operator (both European and national) should be given appropriate

⁴⁴ Checklists for follow-up measures can be found in section 3.4.1 of the Toolbox.

⁴⁵ See previous footnote 39. A RAPEX contact point is available in and can provide advice to all Member States via http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/docs/rapex_contact_points_en.pdf.

⁴⁶ Examples of correspondence with Economic Operator and notifying bodies can be found in section 3.4.2 and 3.4.3 of the Toolbox.

⁴⁷ Examples of a Market Surveillance Authority contacting an Economic Operator located outside of their own jurisdiction can be found in sections 5.1, 5.2, 5.3 and 5.4 of the Toolbox. In the case presented in section 5.1 the issue was resolved via voluntary measures.

time to respond⁴⁸ and can provide an explanation concerning the Market Surveillance Authority's findings or suggest corrective actions which may have already started.

Step 6: The Market Surveillance Authority must use the information received from the Economic Operator to review the compliance and risk assessment that was carried out. The information may mitigate the original result or could lead to a less or more serious result. It is essential that the Market Surveillance Authority subsequently evaluates the suggested actions of the Economic Operator requiring more comprehensive corrective actions to be taken when necessary.

Step 7: In accordance with Article 18(2) of Regulation (EC) 765/2008 the Market Surveillance Authority must assess whether the Economic Operator has carried out the agreed voluntary actions in full. Successful completion of these actions should ensure that the issue of non-compliance has been resolved and that further products placed on or entering the market will be compliant.

Step 8: If steps 2 and 3 of the follow up procedures have already been taken then the Market Surveillance Authority will move to step 14, if not to step 9.

Step 9: Following an assessment of the voluntary actions taken by the Economic Operator the Market Surveillance Authority will decide whether further corrective action is needed or whether the case can be closed.

Step 10: The Market Surveillance Authority can require further corrective actions to be taken where voluntary actions are not sufficient to prevent non-compliant products being placed on the market or to mitigate the risks of non-compliant products already placed on the market.

Further corrective actions will be based on specific European and national legislation as well as those defined in Regulation (EC) No 765/2008 which includes:

- restrictions for placing products on the market or bringing products into compliance;
- stopping products being placed on the market;
- withdrawal of products;
- recall of products.

These measures can be required from the Economic Operator regardless of their location, but can only be enforced when there is an offence in the Market Surveillance Authority's own jurisdiction⁴⁹. Cross-border cooperation will be necessary in cases where the Economic Operator is not located within the Market Surveillance Authority's Member State.

Step 11: A non-compliance can be considered as "formal without risk" when it is limited to formal requirements only (for instance if information on traceability and markings is missing or affixed incorrectly as regards its design, size visibility or legibility *and* that there are no

⁴⁸ Article 21(3) of Regulation (EC) No 765/2008.

⁴⁹ Examples of measures taken by Market Surveillance Authorities against an Economic Operator located outside their own jurisdiction can be found in sections 5.2, 5.3 and 5.4 of the Toolbox.

other reasons to believe that the product presents a risk⁵⁰). In this case the Market Surveillance Authority, after taking appropriate measures to restrict the marketing of the product, will inform other Member States and the European Commission by uploading all available information on ICSMS (see step 14).

Step 12: If the voluntary measures taken by the Economic Operator in step 7 are satisfactory and resolve the issue, the Market Surveillance Authority will make this clear via ICSMS.

Step 13: The Market Surveillance Authority will assess whether it is appropriate and proportionate to impose sanctions (penalties according to national law) following the Economic Operator's corrective actions.

Step 14: If the product presents a risk to the health or safety of persons or to other aspects of public interest protection covered by the legislation on which the assessment is based and is not restricted to their national territory, the Market Surveillance Authority will immediately inform the European Commission and other Member States via ICSMS about the measures in place to prohibit or restrict the product being made available on their national market, to withdraw the product from that market or to recall it. If the product is sold in different Member States, the Market Surveillance Authority shall extend the adopted measures to other national Economic Operators. If it appears that the product presents a serious risk, the Market Surveillance Authority shall issue a RAPEX notification.

Step 15: Information on measures taken against other Economic Operators regarding the same product should be uploaded to ICSMS to ensure a comprehensive exchange of information. If the product presents a serious risk other Market Surveillance Authorities should have issued a RAPEX reaction as a follow up to the measures initially notified in the system.

Step 16: If the product does present a risk, and objections are raised against the measures adopted by the initiating Market Surveillance Authority, the case shall be assessed by the European Commission under the Union Safeguard Clause Procedure.

Step 17: If no objections are raised the measures are deemed to be valid and should be enforced by all other Market Surveillance Authorities where the product was made available.

3.4.2. Union Safeguard Clause Procedure

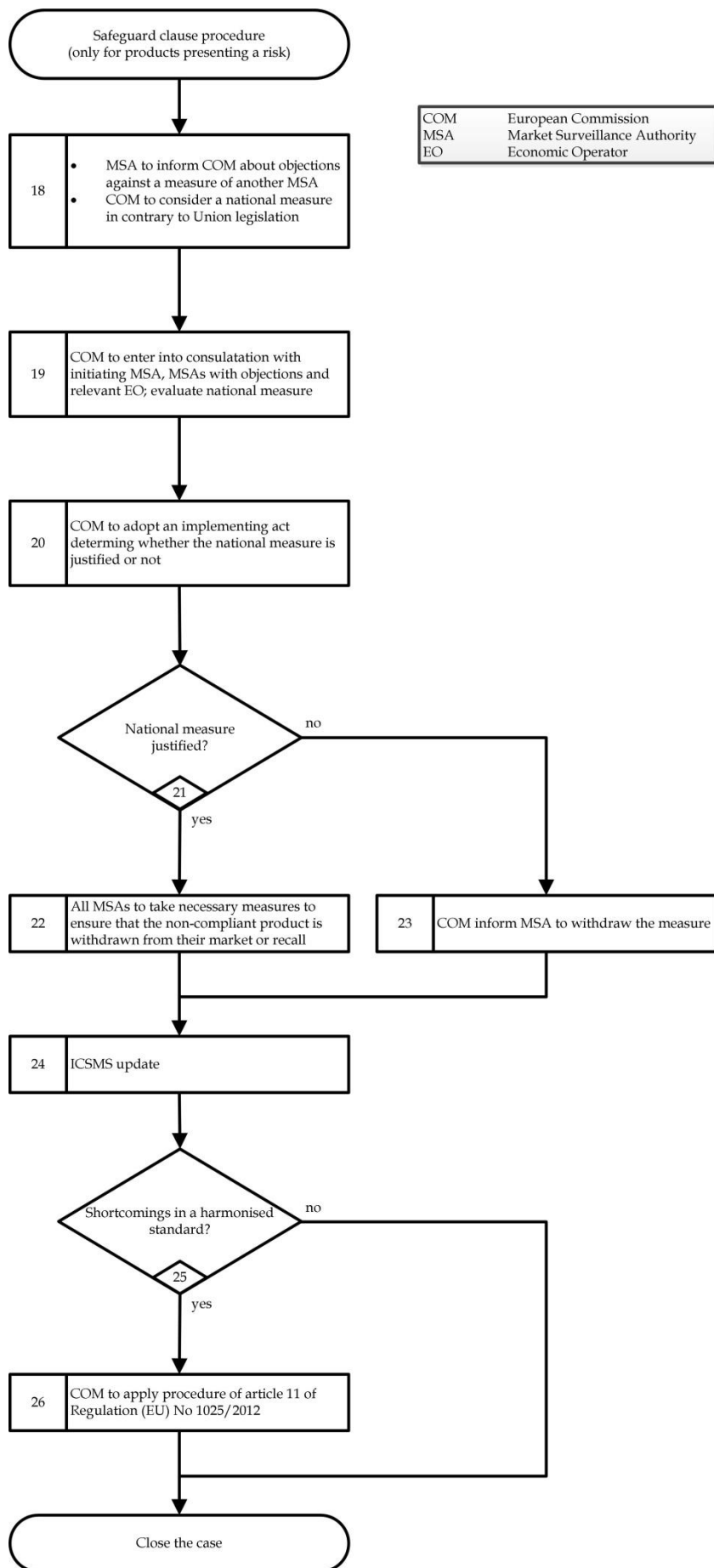
Decision No 768/2008/EC sets out a Union Safeguard Clause Procedure⁵¹ applicable when an objection is raised to the restrictive measures notified by a Market Surveillance Authority.

The Safeguard Clause Procedure is designed to allow the European Commission to take a position on national measures restricting the free movement of products with a view to ensuring the functioning of the internal market.

The following flowchart explains the Safeguard Clause Procedure and the necessary steps to be taken.

⁵⁰ In cases where the CE marking or other required markings are missing the Market Surveillance Authority has reasons to believe that the non-compliance goes beyond this formal requirement and the product presents a risk. Therefore it will move to step 14. See also section 7.4.5 of the Blue Guide.

⁵¹ The following procedure is only relevant for sector legislation aligned to the model set out in Decision No 768/2008/EC. Sector legislation not yet harmonised with Decision 768/2008 will have a different procedure



Step 18: The Safeguard Clause Procedure is initiated if an objection from another Market Surveillance Authority is made via ICSMS within three months⁵² from the notification by the initiating Market Surveillance Authority or if within the same period the European Commission informs the Market Surveillance Authority, through ICSMS, that the measure might be contrary to EU law.

Step 19: The European Commission will:

- consult with all Market Surveillance Authorities and relevant Economic Operators without delay, via suitable means, in writing to ensure that the Market Surveillance Authority is kept informed of any responses from the Economic Operator.
- evaluate the measure taking into account the consultations held with the Market Surveillance Authority and the Economic Operator.
- decide whether the national measure is justified or not on the basis of the evaluation of the measure.

Step 20: The European Commission will adopt and communicate its decision to all Market Surveillance Authorities and the Economic Operator and update ICSMS accordingly.

Step 21: The European Commission informs the Market Surveillance Authority if the measure is considered to be justified or if the Market Surveillance Authority has to withdraw the measure.

Step 22: If the measure is considered justified, all Market Surveillance Authorities must take the necessary measures to ensure that the non-compliant product is withdrawn from the market or recalled from the end-user and inform the European Commission accordingly.

Step 23: If the measure is considered unjustified, the initiating Market Surveillance Authority must withdraw the measure and any associated RAPEX notifications.

Step 24: The Market Surveillance Authority should upload any information about national measures (whether upheld or withdrawn) to ICSMS.

Step 25: The European Commission shall assess whether a measure is attributed to shortcomings in a harmonised standard.

Step 26: Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards, the European Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 concerning the formal objection to harmonised standard.

⁵² Unless otherwise specified in sector-specific EU harmonisation legislation

4. COOPERATION WITH BORDER CONTROL AUTHORITIES (CUSTOMS)

Articles 27 to 29 of Regulation (EC) 765/2008 on Accreditation and Market Surveillance establish obligations to carry out controls on products entering the EU market and establish the legal basis for the cooperation between authorities responsible for border controls (Customs) and Market Surveillance Authorities.

Border controls are an efficient tool to carry out market surveillance on products before they enter the Single Market. Customs, in cooperation with Market Surveillance Authorities can set up filters (e.g. name of manufacturer, product type, name of importer, etc.) according to the Combined Nomenclature codes⁵³ used in the EU customs database TARIC⁵⁴.

National provisions concerning the role of Customs vary as in some member states Customs are a Market Surveillance Authority, in others they are not.

However, in all Member States cooperation between Customs, (which can screen goods at the port of entry and suspend the release for free circulation of those suspected to be non-compliant) and Market Surveillance Authorities (which can assess the compliance of products and require appropriate corrective action) is essential to ensure that both authorities' respective activities are complementary and effective. To facilitate this, the European Commission (under the lead of DG TAXUD) has prepared some guidelines for import controls in the area of product safety and compliance⁵⁵.

The cooperation between Market Surveillance Authorities and Customs might be based on written agreements or other arrangements e.g. on which product areas to focus on, how information will be exchanged (e.g. Market Surveillance Authority contact information including phone numbers and e-mail addresses) and how often the agreement will be reviewed and evaluated.

Aspects such as what procedure to follow for the destruction of products, who bears the costs of destruction and storage of products while not released for free circulation, should be clarified in national legislation.

In order for cooperation to be effective the Market Surveillance Authority seeking assistance on specific campaigns should provide customs inspectors with training and or tools (e.g. a check-list) to detect product specific non-compliance.

To enable customs officers to perform their tasks, the European Commission together with individual Market Surveillance Authorities and through AdCos have prepared checklists and information sheets summarizing EU legal requirements applicable to certain categories

⁵³ Further information on Combined Nomenclature codes can be found via http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/combined_nomenclature/index_en.htm.

⁵⁴ TARIC, the integrated Tariff of the European Union, is a multilingual database in which are integrated all measures relating to EU customs tariff, commercial and agricultural legislation. By integrating and coding these measures, the TARIC secures their uniform application by all Member States and gives all Economic Operators a clear view of all measures to be undertaken when importing into the EU or exporting goods from the EU. It also makes it possible to collect EU-wide statistics for the measures concerned. Further information on TARIC can be found via http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm.

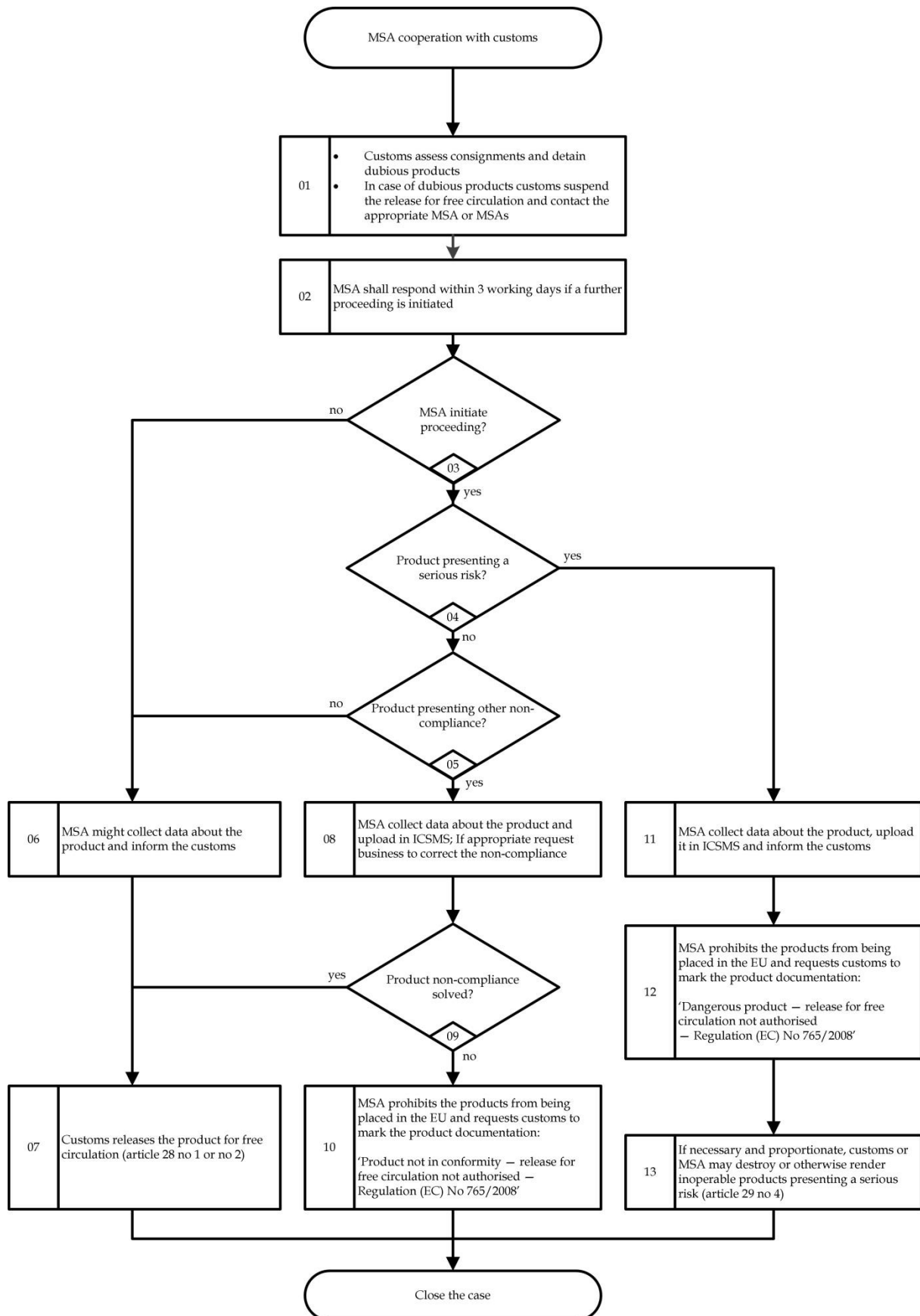
⁵⁵ https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/guidelines_en.pdf.

of goods.⁵⁶ Furthermore it developed a common risk based approach to customs' product safety and compliance controls in order to set up risk profiles⁵⁷. Following the proposed approach Market Surveillance Authorities can ask Customs to set up risk profiles, with relevant criteria e.g. name of manufacturer or importer, product type etc. on specific products.

The following flowchart explains the process and the necessary steps to be taken when cooperating with Customs.

56 Market surveillance and customs officers can obtain a copy of the these documents either via their national representatives at "Customs 2020 project group on product safety and compliance controls on imported goods" managed by DG TAXUD or by requesting it from taxud-unit-b1@ec.europa.eu. Templates for checklists and information sheets can be found in section 4 of the Toolbox.

57 See the document "Cooperation between Customs and Market Surveillance Authorities on risk management in the area of product safety and compliance controls on imported goods" final version of 11 November 2015. Market surveillance and customs officers can obtain a copy of the document either via their national representatives at "Customs 2020 project group on product safety and compliance controls on imported goods" managed by DG TAXUD or by requesting it from taxud-unit-b1@ec.europa.eu.



Step 1: If Customs suspect that a product is non-compliant they will contact the Market Surveillance Authority. To enable this, the Market Surveillance Authority must provide and maintain contact information.

Steps 2 – 3: Although the Market Surveillance Authority does not need to make an immediate decision regarding the compliance of the product they shall respond within 3 working days to inform Customs whether they intend to act on the information or not. If the Market Surveillance Authority does not respond within this period Article 28(1) of Regulation (EC) No 765/2008 states that Customs shall release the product.

Step 4: The Market Surveillance Authority assesses whether the product presents a serious risk.

Step 5: The Market Surveillance Authority assesses whether the product presents other non-compliances.

Step 6: It can be useful for Market Surveillance Authorities to collect data on products in order to identify trends and patterns on which to base future proactive market surveillance activities

Step 7: If a Market Surveillance Authority does not identify non-compliance or if non-compliance identified has been solved by means of appropriate corrective action Customs shall release the product for free circulation.

Step 8: To inform other Market Surveillance Authorities about a non-compliant product found during checks at border controls, all available information about this product should be uploaded to ICSMS.

Where the Market Surveillance Authority finds that a product does not comply with EU harmonisation legislation they shall take appropriate action to ensure the product is brought into conformity or, if necessary, to prohibit placing on the market⁵⁸.

Step 9: If the product is brought into compliance from the Economic Operator (if possible, some requirements can only be brought into compliance by the manufacturer i.e. CE mark), then it is possible to release the product for free circulation (see Step 8).

Step 10: Where placing on the market is prohibited, the Market Surveillance Authority shall require Customs in charge of external border controls not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself⁵⁹:

‘Product not in conformity – release for free circulation not authorised – Regulation (EC) No 765/2008’.

Step 11: In order to inform other Market Surveillance Authorities about products found during border controls that present a serious risk, available information about this product should be collected and uploaded in ICSMS. A RAPEX procedure should follow in cases

⁵⁸ Article 29 of Regulation (EC) No 765/2008

⁵⁹ See Article 29(2) of Regulation (EC) No 765/2008.

where the serious risk has not been made public.

Step 12: Where the Market Surveillance Authority finds that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself⁶⁰:

‘Dangerous product — release for free circulation not authorized — Regulation (EC) No 765/2008’.

Step 13: If national law permits, destruction of a product might be appropriate where the serious risk cannot be rectified.

⁶⁰ See Article 29(1) of Regulation (EC) No 765/2008.

ANNEX 1: List of sectorial legislation

Product sectors	Relevant legislation ^{61 62}
Medical devices (including In vitro diagnostic medical devices and Active implantable medical devices)	Directives 93/42/EEC, 98/79/EC and 90/385/EEC
Cosmetics	Regulation (EC) 1223/2009
Toys	Directive 2009/48/EC
Personal protective equipment	Directive 89/686/EEC - Regulation (EU) 2016/425
Construction products	Regulation (EU) 305/2011
Aerosol dispensers	Directive 75/324/EEC,
Simple pressure vessels and Pressure equipment	Directives 2009/105/EC and 97/23/EC. Directives 2014/29/EU and 2014/68/EU
Transportable pressure equipment	Directive 2010/35/EU
Machinery	Directive 2006/42/EC
Lifts	Directive 1995/16/EC - Directive 2014/33/EU
Cableways	Directive 2000/9/EC - Regulation (EU) 2016/424
Noise emissions for outdoor equipment	Directive 2000/14/EC
Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres	Directive 1994/9/EC - Directive 2014/34/EU
Pyrotechnics	Directive 2007/23/EC - Directive 2013/29/EU
Explosives for civil uses	Directive 93/15/EEC - Directive 2014/28/EU
Appliances burning gaseous fuels	Directive 2009/142/EC - Regulation (EU) 2016/426
Measuring instruments, Non-automatic weighing instruments, Pre-packaged products and Units of measurement	Directives 2004/22/EC and 2009/23/EC - Directives 2014/32/EU and 2014/31/EU; Directives 2007/45/EC, 75/107/EEC and 76/211/EEC; Directive 80/181/EEC

⁶¹ For ease of reference this table indicates established EU legislation. New legislation replacing that listed in the table should be also taken into account for the relevant period in which it is applicable.

⁶² For ease of reference in some cases (e. g. eco-design, energy labelling), this table only indicates EU framework legislation, but is intended to cover also product-specific EU legislative acts.

Product sectors	Relevant legislation^{61 62}
Electrical equipment under EMC Directive	Directive 2004/108/EC - Directive 2014/30/EU
Radio and telecom terminal equipment under RTTE Directive - Radio equipment under RED	Directive 1999/5/EC - Directive 2014/53/EU
Electrical appliances and equipment under LVD	Directive 2006/95/EC - Directive 2014/35/EU
Electrical and electronic equipment under RoHS and WEEE and batteries	Directives 2011/65/EU, 2002/96/EC and 2006/66/EC
Chemical substances under REACH Regulation	Regulations (EC) 1907/2006
Eco-design and Energy Labelling; Efficiency requirements for hot-boilers fired with liquid or gaseous fuels	Directives 2009/125/EC and 2010/30/EU; Directive 1992/42/EEC
Tyre labelling	Regulation (EC) 1222/2009
Recreational craft	Directive 1994/25/EC - Directive 2013/53/EU
Marine equipment	Directive 96/98/EC -Directive 2014/90/EU
Non-road mobile machinery	Directive 97/68/EC
Fertilisers	Regulation (EC) 2003/2003
Biocides	Regulation (EU) 528/2012
Textile and Footwear labelling	Regulation (EC) 1007/2011 and Directive 94/11/EC
Crystal glass	Directive 69/493/EEC

ANNEX 2: Establishing a model for cross-border cooperation under the current rules

<http://ec.europa.eu/DocsRoom/documents/17108/attachments/1/translations>

ANNEX 3: Glossary

Term / Abbreviation	Definition	Source
Accreditation	An attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.	Regulation (EC) No 765/2008
AdCo group	Administrative cooperation group. An informal group supported by the European Commission, consisting of members appointed by Member States and representing national authorities competent for market surveillance in a given sector. A group meets regularly to discuss market surveillance issues in its area of competence and to ensure efficient, comprehensive and consistent market surveillance.	http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups/index_en.htm
ATEX	Directive on Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres.	Directive 2014/34/EU
Authorised representative	Any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Union legislation.	Regulation (EC) No 765/2008

Term / Abbreviation	Definition	Source
Blue Guide	The Blue Guide on the implementation of EU products rules. Guidance document intended to contribute to a better understanding of EU product rules and to their more uniform and coherent application across different sectors and throughout the single market.	Blue Guide (ec.europa.eu/DocsRoom/documents/18027)
CE marking	A marking by which a manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.	Regulation (EC) No 765/2008
CN	Combined nomenclature. A method for designating goods and merchandise which was established to meet, at one and the same time, the requirements both of the Common Customs Tariff and of the external trade statistics of the Union.	ec.europa.eu/taxation_customs
Compliance assessment	The procedure followed by a market surveillance authority to verify if a product complies with the applicable requirements of the Union harmonisation legislation.	Blue Guide
Compulsory measure	A specific restrictive measure imposed by a market surveillance authority.	Regulation (EC) No 765/2008
Conformity assessment	The process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.	Regulation (EC) No 765/2008

Term / Abbreviation	Definition	Source
Conformity assessment body	A body that performs conformity assessment activities including calibration, testing, certification and inspection.	Regulation (EC) No 765/2008
CPR	Construction Products Regulation.	Regulation (EU) No 305/2011
Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.	Regulation (EC) No 765/2008
DoC	Declaration of conformity.	
EEA	The European Economic Area.	
EMCD	Electromagnetic Compatibility Directive.	Directive 2014/30/EU
EO	Economic operator. Means a manufacturer, authorised representative, importer or distributor.	Regulation (EC) No 765/2008
EU	The European Union.	
EU type examination	The part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.	Decision No 768/2008/EC

Term / Abbreviation	Definition	Source
Formal non-compliance	<p>Unless there are reasons to believe that the product presents a risk, one of the following non-compliances with a number of administrative or formal requirements are defined as formal non-compliance by Union harmonisation legislation:</p> <p>(a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;</p> <p>(b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;</p> <p>(c) the technical documentation is incomplete or unavailable;</p> <p>(d) the required labelling or instructions for use are incomplete or missing.</p>	Decision No 768/2008/EC and corresponding provisions in Union harmonisation legislation; Blue Guide
GPSD	General Product Safety Directive.	Directive 2001/95/EC
Harmonised standard	A standard adopted by one of the European standardisation organisations listed in Annex I of Regulation (EU) No 1025/2012 upon a request made by the European Commission for the application of Union harmonisation legislation.	Regulation (EC) No 765/2008, Blue Guide
ICSMS	Information and Communication System for the pan-European Market Surveillance. A general information support system set up by the European Commission for the exchange of information between market surveillance authorities according to Article 23 of Regulation (EC) No 765/2008.	

Term / Abbreviation	Definition	Source
IMP-MSG	Expert Group on the Internal Market for Products. A group whose mission is to develop the cooperation mechanisms between the Member States, in particular between customs and market surveillance authorities and to develop appropriate measures for the optimal use of resources. The members of the group are national administrations responsible for the coordination of market surveillance activities within a Member State.	ec.europa.eu/growth
Importer	Any natural or legal person established within the Union who places a product from a third country on the Union market;	Regulation (EC) No 765/2008
LVD	Low Voltage Directive (Directive on electrical equipment designed for use within certain voltage limits).	Directive 2014/35/EU
Making available on the market	Any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	Regulation (EC) No 765/2008
Market surveillance	The activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;	Regulation (EC) No 765/2008
MD	Machinery Directive.	Directive 2006/42/EC

Term / Abbreviation	Definition	Source
Manufacturer	Means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.	Regulation (EC) No 765/2008
MI	Measuring Instruments Directive.	Directive 2014/32/EU
MS	Member State. One of the sovereign nation states that have acceded to the European Union. For the purpose of this document, the term also applies to countries of the EEA and, if appropriate, to Switzerland.	Interactive Terminology for Europe database (iate.europa.eu)
MSA	Market surveillance authority. An authority of a Member State responsible for carrying out market surveillance on its territory.	Regulation (EC) No 765/2008
National accreditation body	The sole body in a Member State that performs accreditation with authority derived from the State.	Regulation (EC) No 765/2008
Notified Body	A conformity assessment body which is notified by the Member States to the European Commission.	Decision No 768/2008/EC
PED	Pressure Equipment Directive.	Directive 2014/68/EU
Peer evaluation	A process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Regulation, and, where applicable, additional sectoral technical specifications.	Regulation (EC) No 765/2008

Term / Abbreviation	Definition	Source
Placing on the market	The first making available of a product on the Union market;	Regulation (EC) No 765/2008
PPE	Personal Protective Equipment Directive.	Directive 89/686/EEC
Random check	An assessment carried out on a sample of the product or products. The sample is selected at random and not based on visual or suspicious or other evidence of possible defects.	Task force's definition
RAPEX	Rapid Alert System. A system used according to article 22 of Regulation (EC) No 765/2008 and articles 11 and 12 of the General Product Safety Directive. It enables a quick exchange of information between 31 European countries and the European Commission about dangerous non-food products posing a risk to health and safety of consumers and other users.	ec.europa.eu/consumers
RCD	Recreational Craft Directive.	Directive 2013/53/EU
Recall	Any measure aimed at achieving the return of a product that has already been made available to the end user.	Regulation (EC) No 765/2008
RED	Radio Equipment Directive.	Directive 2014/53/EU

Term / Abbreviation	Definition	Source
Release for free circulation	The procedure which confers on non-Union goods the customs status of Union goods, entailing application of commercial policy measures, completion of the formalities laid down in respect of the import of the goods, and the collection of any duty legally due.	Regulation (EU) No 952/2013
Restrictive measures	Any measure taken, pursuant to the relevant Union harmonisation legislation, to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.	Regulation (EC) No 765/2008
R&TTED	Radio and Telecommunication Terminal Equipment Directive.	Directive 1999/5/EC
Union Safeguard clause procedures	Specific procedures establishing whether or not a national measure restricting the free movement of a product is justified. Those procedures apply following the exchange of information on measures with regards to products presenting a risk to the health and safety of persons or to other aspects of public interest protection.	Regulation (EC) No 765/2008 Introduction point (32); Decision No 768/2008/EC Introduction point (48) and model Article R32
Single market	The Union market, where people, goods, services and capital can move around as freely as within a single country. Also called the internal market.	europa.eu
SPVD	Simple Pressure Vessels Directive.	Directive 2014/29/EU

Term / Abbreviation	Definition	Source
State of the art	Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience	EN 45020
TARIC code	A code from the Integrated Tariff of the European Union.	Interactive Terminology for Europe database (iate.europa.eu)
TAXUD	Directorate-General for Taxation and Customs Union.	Interactive Terminology for Europe database (iate.europa.eu)
Technical specification	Document that prescribes technical requirements to be fulfilled by a product, process or service. It may be a standard, a part of a standard or independent of a standard.	Regulation (EC) No 765/2008, EN 45020
Third country	A country that is not a Member State of the European Union.	Interactive Terminology for Europe database (iate.europa.eu)
TOYS	Directive on the Safety of Toys.	Directive 2009/48/EC
TPED	Transportable Pressure Equipment Directive.	Directive 2010/35/EU
Union	The European Union.	

Term / Abbreviation	Definition	Source
Union harmonisation legislation	Any Union legislation harmonising the conditions for the marketing of products.	Regulation (EC) No 765/2008
Voluntary measure	An action undertaken by an economic operator before a market surveillance authority actually imposes a specific restrictive measure.	Decision No 768/2008/EC and corresponding provisions in Union harmonisation legislation
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market.	Regulation (EC) No 765/2008

ANNEX 4: Additional sources of relevant information

A vision for the internal market for industrial products:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3A240302_4

AdCo administrative cooperation groups, including their guides (documents from AdCo's):

https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_nl

Aligned legislation:

https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

ATEX:

http://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en

Blue guide:

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=7326

Cableways:

http://ec.europa.eu/growth/sectors/mechanical-engineering/cableways_en

Combined nomenclature:

http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/combined_nomenclature/index_en.htm

Construction:

https://ec.europa.eu/growth/sectors/construction_en

Ecodesign and Energy labelling:

http://ec.europa.eu/growth/industry/sustainability/ecodesign_en

Electromagnetic compatibility (EMC):

https://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive_en

Fertilizing products:

http://ec.europa.eu/growth/sectors/chemicals/legislation_en

Gas appliances:

https://ec.europa.eu/growth/sectors/pressure-gas/gas-appliances_en

Good Practice in Market Surveillance Activities related to Non-Food Consumer Products sold Online:

<http://ec.europa.eu/DocsRoom/documents/8724?locale=nl>

Guidelines for import controls in the area of product safety and compliance:

https://ec.europa.eu/taxation_customs/sites/taxation/files/docs/body/guidelines_en.pdf

Harmonised standards:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_nl

Legal metrology:

http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology_en

Lifts:

http://ec.europa.eu/growth/sectors/mechanical-engineering/lifts_en

Low voltage (LVD):

https://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive_en

Machinery:

http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en

Measuring instruments:

http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/measuring-instruments_en

Medical devices:

https://ec.europa.eu/growth/sectors/medical-devices_en

Multi-annual action plan for the surveillance of products in the EU :

<http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52013DC0076>

NANDO:

<http://ec.europa.eu/growth/tools-databases/nando/>

New legislative framework (Regulation 765/2008, Decision 768/2008 and aligned legislation):

https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

OECD Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections:

<http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm>

Personal protective equipment (PPE):

http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en

Pressure equipment:

https://ec.europa.eu/growth/sectors/pressure-gas/pressure-equipment_en

Prosafe best practices techniques in market surveillance:

<http://www.prosafe.org/library/knowledgebase/item/best-practices-techniques-in-market-surveillance>

Radio and telecommunication terminal equipment (R&TTE) and new radio equipment (RED) directives:

https://ec.europa.eu/growth/sectors/electrical-engineering/rtte-directive_en

Rapex guidelines (including risk assessment guideline):

http://ec.europa.eu/consumers/archive/safety/rapex/docs/rapex_guid_26012010_en.pdf

Recreational craft:

https://ec.europa.eu/growth/sectors/maritime/recreational-crafts_en

Risk assessment methodology (EU general risk assessment methodology):

<http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations>

Taric database:

http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm

Toys :

https://ec.europa.eu/growth/sectors/toys_en

Treaty guidance:

<http://ec.europa.eu/growth/single-market/goods/building-blocks/>

United Nations Economic Commission for Europe (UNECE) Advisory Group on Market Surveillance (MARS):

<http://www.unece.org/trade/wp6/sectoralinitiatives/mars/mars.html>

WELMEC European cooperation in legal metrology guides:

<http://www.welmec.org/latest/guides/>